

STANDARD

6475

First edition
1989-11-01

**Implants for surgery — Metal bone screws with
asymmetrical thread and spherical under-surface
— Mechanical requirements and test methods**

*Implants chirurgicaux — Vis métalliques à filetage asymétrique et à embase
sphérique pour os — Caractéristiques mécaniques et méthodes d'essai*



Reference number
ISO 6475 : 1989 (E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 6475 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This first edition of ISO 6475 cancels and replaces the first editions of ISO 6475-1 : 1980 and ISO 6475-2 : 1980, of which it constitutes a revision and amalgamation.

Annex A forms an integral part of this International Standard. Annexes B and C are for information only.

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Introduction

This International Standard does not purport to address all of the safety problems associated with its use. It is the responsibility of whoever uses it to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

The results obtained in this method bear no direct correlation to the use of the subject bone screw. This test method is used only for purposes of maintaining the uniformity of the product tested.

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Implants for surgery — Metal bone screws with asymmetrical thread and spherical under-surface — Mechanical requirements and test methods

1 Scope

This International Standard specifies the test methods for determining breaking torque and angle of rotation at failure for metal bone screws for surgery. Mechanical requirements for bone screws are specified in annex A.

NOTES

1 At present data are only available for bone screws with dimensions according to ISO 5835 and made from stainless steel according to ISO 5832-1. If data become available for bone screws made from other materials and/or with other standardized dimensions, they will be added in further annexes.

2 The interrelationship of International Standards dealing with bone plates, bone screws and relevant tools is shown for information in annex B.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 5832-1 : 1987, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*.

ISO 5835 : — ¹⁾, *Implants for surgery — Metal bone screws with hexagonal drive connection — Spherical under-surface of head, asymmetrical thread — Dimensions*.

3 Test method

3.1 Apparatus

A test machine having the following characteristics shall be used :

- a) a maximum sensitivity on the lowest measuring range of not less than 0,01 N·m or equivalent, and on other scales of not less than 1 % of full scale reading;
- b) a selection of measuring ranges (see 3.2.4);
- c) the capability of recording the maximum torque attained during the test;
- d) a device to prevent the screw becoming disengaged from the component by means of which the torque is applied.

NOTE — In some countries the test machine must comply with the requirements laid down by the national test or verification authority.

3.2 Procedure

3.2.1 Insert the screw under test into the test block and clamp it so that the following conditions are met :

- a) if possible, five full threads from the thread run-out shall be exposed;
- b) movement of the clamped portion shall be prevented;
- c) the axes of the screw and the component by means of which the torque is applied shall be coincident.

1) Will cancel and replace ISO 5835-1 at next revision stage. (ISO 5835-1 cancelled and replaced ISO 5835-1 : 1978 and ISO 5835-2 : 1978.)